

Food and Drug Administration Rockville MD 20857

FEB 2 4 2005

Gerald Austin c/o Eva Kasparova Sezimova 9 14000 Prague 4 CZECH REPUBLIC

Re: Docket No. 2004P-0411/CP1

Dear Mr. Austin:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on September 8, 2004. Your petition requests that the Agency compel the enforcement and regulation of amyl nitrite pursuant to 21 CFR 250.100 as it relates to specific internet websites.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely, Jane a. Afelias

Jane A. Axelrad

Associate Director for Policy

Center for Drug Evaluation and Research

20048-0411

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